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10/552,593	11/10/2006	Carsten Momma	117163.00150	2507

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EXAMINER	
HIGGINS, GERARD T	

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
10/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/552,593	MOMMA ET AL.	
	Examiner	Art Unit	
	GERARD T. HIGGINS	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 08/15/2008 has been entered. Currently claims 1-18 and 20 are pending. Please note that although applicants list claim 19 as withdrawn on their listing of claims, they state in their Remarks that claim 19 should be cancelled. In the sense of expediting prosecution, the Examiner will treat claim 19 as cancelled and requests the listing of claims to reflect as such in the next submission by applicants.

Claim Objections

2. Applicant is advised that should claim 3 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof; furthermore, should claim 4 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims do not differ in wording and with the amendment to claim 3; the claims are now identical limitations.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claim 6, the Examiner does not find support in the specification as filed for ***any*** of the limitations of claim 6; for example, the phrase "wherein the radiopaque material is attached to the carrier structure by the cover layer."

With regard to claim 7, the Examiner does not find support for the limitation "wherein the cover layer comprises a hollow wire and the marker element comprises radiopaque material filling the hollow wire." Applicants are not supported for all types of hollow wires as is seen at [0011] of their specification or throughout the specification as a whole; further, they are not supported for all types of radiopaque material filling said hollow wire as seen at [0011] or throughout their specification as a whole. Lastly, there is no mention that “the cover layer comprises a hollow wire” either at [0011] or in the specification as a whole.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-4, 6-11, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 2, the phrase “wherein the carrier structure includes legs and apertures ***for*** marker elements” renders the claim indefinite. It is unclear how legs and apertures are acting as marker elements. Are there two different types of marker elements in this invention?

With regard to claim 6, the phrase “wherein the metallic carrier structure is formed from the metal or the metal compound which the cover layer includes” renders the claim indefinite. It is unclear what this phrase means.

With further regard to claim 6, the phrase “wherein the radiopaque material is attached to the carrier structure by the cover layer" renders the claim indefinite. It is unclear how the cover layer is helping the radiopaque material to attach and/or what function it is performing.

With regard to claim 7, the phrase "wherein the cover layer comprises a hollow wire" renders the claim indefinite. It is unclear how it can ***comprise*** a hollow wire.

With regard to claim 8, it recites the limitation "the wire" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Perhaps applicants meant “the hollow wire.”

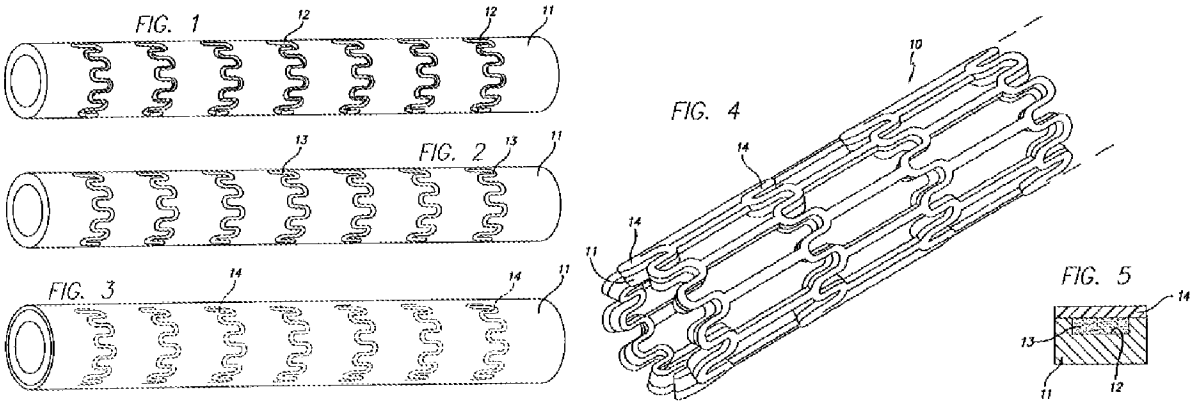
Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 6-13, 15, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dang (6,471,721).

With regard to claims 1, 2, and 7, Dang discloses the device of Figures 1-5.



The stent comprises a radiolucent carrier structure (col. 3, lines 22-31 and col. 5, lines 12-23). The device may have radiopaque marker element **13**, which includes comparatively radiopaque material incorporated therein (col. 5, lines 38-41). The marker element is attached to the rest of the carrier structure **10**, and the radiopaque material is completely enclosed with a cover layer **14** and **11**, which may include a metal (col. 5, line 65 to col. 6, line 17). The cover layer has the same resultant structure as a hollow wire into which the radiopaque material fills the core thereof. The device can be

self-expanding as taught by Dang at col. 1, lines 24-26, where they state that the stent may be deployed "automatically by the removal of a restraint." The device may be comprised of nitinol, which is a nickel-titanium alloy (col. 3, lines 22-30).

With regard to claim 2 and the marker elements being welded into apertures that then comprise the legs; since the ***entirety*** of the stent includes the radiopaque material enclosed by the cover layer, this is equivalent to applicants' suggestion of welding the marker elements as welded into apertures to comprise said legs. Each small leg or connecting piece in the longitudinal direction in the overall structure of Figure 4 may be interpreted to be a marker element; furthermore, the requirement that the marker elements be welded into apertures is a product-by-process limitation. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Please see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Given that the device of Dang has legs that comprise the radiopaque material completely enclosed by a cover layer identical to that claimed, the Examiner deems the device of Dang to anticipate applicants' claimed device.

With regard to claims 3, 11, and 13, the device may be comprised of nitinol, which is a nickel-titanium alloy. The device can be self-expanding as taught by Dang at

col. 1, lines 24-26, where they state that the stent may be deployed "automatically by the removal of a restraint."

With regard to claim 6, Dang discloses at col. 5, lines 14-23 that the materials for the carrier substrate include *inter alia* 316L stainless steel and nitinol. They go on to disclose at col. 6, lines 9-11 that while one preferred material for the layer **14** "is 316L stainless steel, other suitable material can be used." The Examiner deems that since 316L stainless steel may be used for the carrier structure and the covering layer that nitinol would be a "suitable material" for the layer **14** and **11**.

With regard to claims 8-10, 15, and 16, the radiopaque material is incorporated throughout the stent as seen in Figures 1-4. Also the radiopaque material comprises the core of the carrier structure and cover layer (lumen of a tube) as seen in Figure 5. It is clear from the Figures that the radiopaque material comprises at least part of the carrier structure; furthermore, since the radiopaque is incorporated throughout the stent it will necessarily be incorporated in the region of a longitudinal end of the stent. The Examiner has deemed laser bonding to be welding; however, in the case that applicants disagree with that assessment, the requirement that the marker elements be welded is a product-by-process limitation. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product

was made by a different process." Please see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regard to claim 12, Dang discloses at col. 5, lines 41-44 that the radiopaque material may be gold or platinum.

With regard to claim 20, the stents of Dang can inherently be placed into a patient; furthermore, Dang discloses at col. 1, lines 14-27 that stents are particularly adapted to be implanted into a patient's body.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,471,721) as applied to claim 3 and 13, respectively, in view of applicants' own admissions.

Dang discloses device that may be comprised of nitinol, which is a nickel-titanium alloy (col. 3, lines 22-30) that is inherently a shape memory metal; however, he does not disclose a device that has a design that may allow for temperature dependent change in the configuration of the stent.

Applicants state that it is known to one of ordinary skill in the art to build stents of certain design that allow for temperature dependent change in the configuration of the stent [0026].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to build a stent of a certain design in order to take advantage of this known temperature dependent change in the configuration of the stent. The results would have been predictable; further, the motivation to use this design would be to remove the need for a restraint mechanism or a balloon to expand the stent. This would lead to a product that was cheaper and much more easily deployed.

11. Claims 5, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,471,721) as applied to claim 1 in view of Kranz et al. (6,312,456).

With regard to claim 5, Dang discloses all of the limitations of applicants' claim 1 in section 14 above, and it also discloses at col. 6, lines 56-57 that a biocompatibility layer may be added; however, it fails to disclose that the biocompatibility layer contains silicon carbide.

Kranz et al. disclose at col. 2, lines 51-54 that silicon carbide is used as an outer coating layer on the biocompatible stent and counteracts thrombosis formation; further, at col. 4, lines 27-30 that the silicon carbide is used as an outer covering to avoid stenosis.

Since Dang and Kranz et al. are both drawn to stents, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use

the silicon carbide outer covering layer of Kranz et al. as the biocompatibility layer of Dang. The motivation for doing so has been stated above and includes *inter alia* counteracting thrombosis formation; further, the overcoating of silicon carbide on the device of Dang would produce a stent that had a multilayered covering layer, and as such would still include the nitinol cover (a metal or metal compound) as well as the additional layer of silicon carbide.

With regard to claim 17, a silicon carbide covering on the entire stent as taught by Kranz et al. would produce a stent that renders obvious applicants' claim 17 because the stent still has marker elements that form at least part of the carrier structure in the region of a longitudinal end of the stent.

With regard to claim 18, the Examiner has deemed laser bonding to be welding; however, in the case that applicants disagree with that assessment, the requirement that the marker elements be welded is a product-by-process limitation. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Please see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

12. Applicant's arguments, see Remarks, filed 08/15/2008, with respect to the objections to the specification, the objections to the claims, the rejection of claims 7-10 under 35 U.S.C. 112, first paragraph, and the rejection of claims 1-19 under 35 U.S.C. 112, second paragraph, and the rejection of claims 1, 5, 12, and 15-20 under 35 U.S.C. 102(b) as being anticipated by Kranz et al. (6,312,456) have been fully considered and are persuasive. The relevant objections/rejections have been withdrawn.

Please note that although rejections have been withdrawn, applicants' amendment have raised new rejections under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 112, second paragraph.

Additionally applicants' amendments have rendered Kranz et al. not applicable to the present claims.

13. Applicant's arguments filed 08/15/2008 have been fully considered but they are not persuasive.

Applicants first attempt to argue that the nitinol carrier structure and cover layer is not inherently self-expanding.

The Examiner respectfully disagrees. The Examiner notes that Dang discloses forming stents that self-expand upon having a restraint removed (col. 1, lines 24-26); however, applicants are correct in noting that the self-expansion of the stent will be

based on design and the Examiner has not shown this type of a design as is claimed in claims 4 and 14. The Examiner has therefore made a new rejection of claims 4 and 14 based upon applicants' own admission. Applicants state that it is known to someone of ordinary skill in the art to design a stent such that it would have a self-expanding carrier structure that would be deployable by utilizing a temperature change [0026].

Applicants also argue that the Examiner has not shown a radiopaque marking element that is comprised of a cover layer that completely encloses the radiopaque material.

The Examiner disagrees that the reference does not teach this; however, the Examiner does agree that he did not properly show a cover layer that completely encloses said radiopaque material. Please note in the rejection above that the cover layer is now parts **14** and **11** in Figure 5 of Dang. This cover layer completely encloses the radiopaque material **13**. Given that the entire stent ***is*** the marking element as well, this therefore means that that the at least partially radiolucent carrier structure has a marker element attached thereto.

With regard to applicants' argument that grooves are not apertures, the Examiner agrees. The meaning of apertures to the Examiner now is places in the carrier structure lacking in legs or other attaching sections; however, the fact that the apertures are filled by welding in marking elements to therefore generate legs or other connecting sections is a product-by-process limitation. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Please see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The fact that the ***entirety*** of the stent is comprised of a carrier structure with marking elements comprised of radiopaque material and cover layers means that the resulting product (a stent with legs or connecting sections comprised of marker elements) of Dang is identical to that claimed.

With regard to claim 7 and applicants' amendment that the "cover layer comprises a hollow wire and the marker element comprises radiopaque material filling the hollow wire," the Examiner directs applicants' attention to the new interpretation of the cover layer/hollow wire as mentioned above (Figure 5 of Dang). The material **13** is the radiopaque marker material and the cover layer is the parts **14** and **11**.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERARD T. HIGGINS whose telephone number is (571)270-3467. The examiner can normally be reached on M-F 9:30am-7pm est. (1st Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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